Corneal Transplant, Not All the Rules Prevent Blindness

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As science and medicine advance, regulations must be updated accordingly. When the rules that govern medicine are so far behind current research that they work against medicines' mission to prevent blindness, it becomes time to reassess and act.

CORNEAL TRANSPLANT

Corneal scarring is a major public health concern and is the leading form of blindness worldwide.[1]Treatment is limited to corneal transplantation, the most commonly performed transplantation worldwide.[1,2] However, the demand for transplant tissue far exceeds the supply. Only one cornea is available for every 70 needed, a deficit that impacts 12.7 million people worldwide.[2,3] This shortage is due to a multitude of factors including the number of corneas, access to corneas, and financial barriers. Developing countries have been shown to have elevated levels of corneal blindness, but often have less developed transplantation services.[4]

The United States and Sri Lanka are the world leaders in corneal export (94%), as many other countries do not have enough corneas to provide for their population[2] A study in 2012, estimated 53.3% of the world's population cannot access and perform corneal transplantation and only 35.7% have access to satisfactory corneal transplantations.[2]

Despite this need, an estimated 3,200 corneal donations from men who have sex with men (MSM) were disqualified in 2018 alone due to a longstanding policy of donation prohibition and deferral in the US and Canada.[5]

Why the Five-Year Deferral Doesn't Make Sense?

In addition to being historically banned from giving blood, MSM have been similarly excluded from donating corneal tissue. In the past, testing for sexually transmitted infections (STIs) was unreliable, predicating a Food and Drug Administration (FDA) policy that required a five-year period of sexual abstinence for MSM before donating blood or organ tissue.[6,7] This policy remains today and the current FDA guidelines and the Eye Bank Association of America medical standards still restrict transplant of corneas from MSM. At present, such a ban is both incongruent with current evidence-based practices and inconsistent with blood and tissue donation regulations applied to non-MSM donors.[5,8] MSM continue to be subject to a five-year deferral period prior to donating corneal tissue, while heterosexual individuals with known HIV exposure are only subject to a one-year deferral period.[9] This policy not only overestimates the risk of contracting HIV through blood or tissue donation but also singles out MSM and contributes to the stigmatization of the MSM community.[5,8]

Why should we rethink this ban?

HIV testing has progressed exponentially since these policies were put into place. Current testing allows reliable detection of HIV 1 to 2 weeks after infection.[10] All corneal tissue donations are now subject to nucleic acid testing

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(NAT), which is 99% accurate and can detect HIV in four to eight days from infection.

Corneas that test positive may be safely and effectively excluded from transplantation without requiring all MSM donors to defer from sexual activity for five years, which inherently excludes most cadaveric donations.[5,11,12] Furthermore, the use of NAT decreases the reliance on social history and medical history screening and permits for a more comprehensive evaluation of all corneas to ensure there are no gaps.[12] One of the flaws with using social and medical history is it may not necessarily be complete. An individual may not have reported their sexual practices and family members may be unaware of their sexual history.

Furthermore, if the individual was being treated for HIV with a treatment drug that causes the patient's viral load to be undetectable (less than 50 copies/mL of blood) then this would also create a gap.[13,14] If a patient has an undetectable viral load and no documented social history then they would be deemed acceptable for corneal transplantation. This demonstrates the present inconsistencies within this FDA policy that do not adequately account for new HIV treatment regimens that are available.

In the event a cornea is transplanted from someone with HIV, according to the Notify Library, a World Health Organization-sponsored international database of all published adverse outcomes on transplantation, there have been no documented cases of HIV transmission through corneal donation, including transmission from donors with known HIV-positive status.[15] Shortening the deferral period to align with current HIV-testing capabilities would both reduce transplant shortages and help to decrease the stigmatization of MSM through a practice of evidence-based medicine.

Moving Forward

Current American Association of Ophthalmology policy states that corneal procurement "should protect recipients from diseases or infections that are potentially transmissible by corneal transplantation" but does not stipulate additional or separate policies for donations from MSM.[16] Medical students of the American Medical Association also advocate for the reduction of the deferral period among MSM, having passed a policy resolution in 2021 that requested that deferral periods for corneal donation be representative of current HIV-testing technology. Many countries, including Spain, Italy, Chile, and Mexico, have no MSM deferral period for corneal donation.[17-19]

In short, an abundance of data demonstrates that the current FDA policy on MSM corneal tissue donors is outdated and no longer evidence based, indicating the time for change. Updated, evidence-based, and non-derogatory policy is vital to increasing opportunities for safe corneal transplantation to reduce preventable blindness worldwide.

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